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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,094	01/09/2006	Christopher J. Ormandy	SPRUS1130 (064206-0601)	1967
30542 7590 11/12/2008 FOLEY & LARDNER LLP P.O. BOX 80278 SAN DIEGO, CA 92138-0278				
EXAMINER				
BORGHEEST, CHRISTINA M				
ART UNIT		PAPER NUMBER		
1649				
MAIL DATE		DELIVERY MODE		
11/12/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,094

Applicant(s)

ORMANDY ET AL.

Examiner

Christina Borgeest

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 14-23, 32-34, 36-41, 43, 44, 53-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Part A.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 4, 5, 14-16, 18, 20, 21, 23, 32, 33, 34, 41 and 43, 44, 53-55 (all in part), drawn to administration of galanin or a functional analog or agonist thereof.

Group II, claim(s) 2, 4, 5, 14-16 (all in part), 17 and 18, 20, 21, 23, 32, 33, 34 (all in part), drawn to administration of galanin or a functional analog or agonist thereof and the additional administration of estrogen or functional analog thereof.

Group III, claim(s) 2, 4, 5, 14-16 (all in part) and 18 (in part), 19 and 20, 21 (in part), 22, and 23, 32, 33, 34 (all in part), drawn to administration of galanin or a functional analog or agonist thereof and the additional administration of prolactin or an analog thereof.

Group IV, claim(s) 36-40, drawn to transgenic mammals.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features for the following reasons. According to 37 CFR 1.475, a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn **only to one** of the following combination of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present. In the instant case, multiple products and uses are claimed.

Groups I-III represent three distinct processes (i.e., methods of treatment) because the steps are non-coextensive. For example, administration of galanin alone is not the same as administration of galanin and estrogen or galanin and prolactin. Three separate processes are not represented by any of the five above-named categories. Second, the transgenic mammals of Group IV do not represent a product using the methods of Groups I-III, and its combination with Groups I-III is not represented by the five above-named categories.

Part B.

This application also contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

GALANIN ANALOGS – RECITED IN CLAIMS 5, 14, 23, 32, 44 AND 53

I-a. SEQ ID NO: 1

- I-b. SEQ ID NO: 2
- I-c. SEQ ID NO: 3
- I-d. SEQ ID NO: 4
- I-e. SEQ ID NO: 5
- I-f. SEQ ID NO: 6
- I-g. SEQ ID NO: 11
- I-h. SEQ ID NO: 12
- I-i. SEQ ID NO: 13
- I-j. Galanin-(2-29)
- I-k. Galanin-(3-29)
- I-l. Galanin-(1-15)
- I-m. Galanin-(1-16)
- I-n. M40: galanin-(1-13)-Pro-Pro-Ala-Leu-Ala-Leu-Ala-amide
- I-o. M35: galanin (1-13)-bradykinin (2-9) amide;
- I-p. M32: galanin (1-13)-neuropeptide Y (25-36) amide
- I-q. C7: galanin(1-13)-spantide amide

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

5, 14, 16, 23, 32, 34, 44, 53, 55.

The following claim(s) are generic: 1, 2, 4, 15, 17-22, 33, 36-43, 54.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species represents a different and non-overlapping product. Groups I-III are drawn to the administration of galanin (as well as other compounds in the case of Groups II-III). Since there are 17 separate galanin analogs named, that means there are 51 different methods of administration.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 8:00am - 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest, Ph.D.

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646